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Motions, Pleadings and Filings

United States District Court,
N.D. Illinois,
Eastern Division.
SMITHKLINE BEECHAM, CORPORATION and Beecham Group, p.l.c., Plaintiffs,
v.
APOTEX CORP., Apotex, Inc., and Torpharm, Inc., Defendants.
No. 98 C 3952.

Dec. 3, 2001.

Owner of patent for antidepressant drug sued manufacturer of generic version for infringement. On cross-motion for summary judgment, the District Court, Kocoras, J., held that: (1) patent was not invalid for failure to name true inventor; (2) patent was not invalid as anticipated; (3) invention was not in public use more than one year prior to patent application date; (4) patent was not invalid as indefinite; and (5) fact issue existed as to whether patent was infringed.

Plaintiff's motion granted; defendant's motion denied.

West Headnotes

[1] **Patents 312(1.2)**
291k312(1.2) Most Cited Cases
Burden of demonstrating invalidity of patent is on party asserting invalidity, and this burden does not shift to patent holder at any point during litigation.

[2] **Patents 314(5)**
291k314(5) Most Cited Cases
Whether patent is invalid because of prior conception is question of law. 35 U.S.C.A. § 102(f).

[3] **Patents 112.1**
291k112.1 Most Cited Cases
Presumption of validity for issued patent includes presumption that original inventor is named. 35 U.S.C.A. § 282.

[4] **Patents 91(4)**
291k91(4) Most Cited Cases
Evidence that holder of patent for hemihydrate version of chemical first identified version in batch made according to methods of third party, who had patented anhydrous version of chemical, was insufficient to establish that third party was true inventor of hemihydrate version; there was no evidence that third party appreciated that it had produced hemihydrate version, or that it communicated that knowledge to patent holder. 35 U.S.C.A. § 102(f).

[5] **Patents 72(1)**
291k72(1) Most Cited Cases
Anticipation of invention occurs when single prior art reference or prior reduction to practice discloses each and every element of claimed invention; if even one element is excluded from prior art reference, there is no anticipation. 35 U.S.C.A. § 102.

[6] **Patents 66(1.12)**
291k66(1.12) Most Cited Cases
Patent for hemihydrate version of chemical was not anticipated by third party's discovery of anhydrous version, even if third party's manufacturing process also produced hemihydrate version, absent evidence third party knew of
existence of hemihydrate version. 35 U.S.C.A. § 102.

[7] **Patents 75**
291k75 Most Cited Cases
Pharmaceutical company's clinical trials of drug constituted experimental rather than public use, within meaning of exception to patentability, even though named inventors did not control trials; trials were closely controlled by inventors' employer and assignee of patent, company received no payments for trials, and period of time of precritical date testing was brief. 35 U.S.C.A. § 102(b).

[8] **Patents 75**
291k75 Most Cited Cases

[8] **Patents 90(5)**
291k90(5) Most Cited Cases
Reduction of invention to practice necessarily ends any effort to perfect invention and ascertain its effectiveness, and thus concludes period during which use may be considered experimental for purposes of "public use" bar to patentability. 35

U.S.C.A. § 102(f).

[9] Patents 75
291k75 Most Cited Cases
Pharmaceutical company had not reduced antidepressant drug to practice more than one year before filing patent application, and thus was not precluded from asserting that precritical date clinical trials were experimental rather than public use, within meaning of exception to patentability; prior animal studies did not prove efficacy of drug in humans, and prior human studies, conducted outside United States, were not accompanied by publication until less than one year before filing of American patent application. 35 U.S.C.A. § 102(b).

[10] Patents 101(6)
291k101(6) Most Cited Cases
Patent claim for antidepressant drug, calling for use of "crystalline paroxetine hydrochloride hemihydrate" without requiring any specific purity level, was not so indefinite that one skilled in art would not understand its bounds, and thus was not invalid. 35 U.S.C.A. § 112, ¶ 2.

[11] Patents 165(1)
291k165(1) Most Cited Cases

[11] Patents 167(1)
291k167(1) Most Cited Cases

[11] Patents 168(2.1)
291k168(2.1) Most Cited Cases
Three sources of information are properly considered in patent claim construction: first and foremost, claims themselves, then specification and prosecution history if claim language is not clear on its face.

[12] Patents 167(1.1)
291k167(1.1) Most Cited Cases
Patents must be read in light of their specifications, without reading limitations from description into claim.

[13] Patents 157(1)
291k157(1) Most Cited Cases
Terms in patent claim are given their ordinary and accustomed meaning.

[14] Patents 165(5)
291k165(5) Most Cited Cases
Under doctrine of "claim differentiation," construing court may not read limitation explicitly set forth in dependent patent claim into independent claim from which it depends.

[15] Patents 162
291k162 Most Cited Cases
Patentee can be his or her own lexicographer, using terms in manner inconsistent with their ordinary meanings.

[16] Patents 165(5)
291k165(5) Most Cited Cases
Other
While two distinct claims cannot ordinarily be read to have same meaning, doctrine of claim differentiation cannot broaden claims beyond scope that is supported by specification.

[17] Patents 101(6)
291k101(6) Most Cited Cases
Patent claims that are difficult to construe are not automatically indefinite; rather, claim must be insolubly ambiguous with no proper narrowing construction before it will be deemed invalid for indefiniteness. 35 U.S.C.A. § 112, ¶ 2.

[18] Patents 249.1
291k249.1 Most Cited Cases
Holder of patent for pharmaceutical drug was not limited to only those tests to which patent specifically referred for determining infringement.

[19] Patents 250
291k250 Most Cited Cases
Time at which composition of generic drug is legally significant for infringement purposes is time of marketing; any changes in chemical composition after product is marketed are not relevant to patent infringement analysis.

[20] Patents 323.2(3)
291k323.2(3) Most Cited Cases
Issues of material fact as to what amount of hemihydrate version of chemical in generic drug consisting mostly of anhydrous version would be infringing of patent for hemihydrate version, and what amount of hemihydrate version was in generic drug at time of marketing, precluded summary judgment on question of infringement.

Patents 328(2)
291k328(2) Most Cited Cases
4,007,196. Cited.

Patents 328(2)
291k328(2) Most Cited Cases
4,721,723. Valid.

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Robert F. Green, Leydig, Voit & Mayer, Ltd., Chicago, IL, for Intervenor.

MEMORANDUM OPINION

KOCORAS, District Judge.

This matter is before the Court on motions for summary judgment regarding the validity of Plaintiffs' patent and noninfringement of that patent by Defendants' proposed drug. For the reasons set forth below, we deny the Defendants' motions. We grant the Plaintiffs' motions on the issue of invalidity under 35 U.S.C. § 102(b), (f), and (g).

BACKGROUND

In the 1970s, scientists at the Danish company of A/S Ferrosan ("Ferrosan") discovered a new class of chemical compounds, at least some of which were reported to selectively inhibit the reuptake of serotonin, a naturally occurring chemical in the brain. Several commercial antidepressants common at the time acted by inhibiting the neuronal reuptake of serotonin, and Ferrosan determined in laboratory tests that the serotonin-uptake inhibitory activity of its new compounds was comparable to that exhibited by these existing antidepressant drugs. Ferrosan then applied for, and on February 8, 1977, was assigned, U.S. Patent No. 4,007,196 ("the '196 patent"). (TP Ex. 4. [FN1]) The patent was entitled "4-PHENYLPIPERIDINE COMPOUNDS;" according to the abstract, it "relate[d] to new 3-substituted 1-alkyl-4-phenylpiperidines, being useful as antidepressant and anti-Parkinson agents, and to their production." (*Id.*)

FN1. The following abbreviations are used in citations throughout this opinion:
• "TP"--TorPharm's Local Rule 56.1(a)(3) Statement of Material Facts in Support of Its Motions for Summary Judgment
• "TP Exh."--TorPharm Exhibits • "SB Resp."--SB's Response to TorPharm's Local Rule 56.1(a)(3) Statement of Material Facts
• "SB Resp. Exh."--Exhibits to SB's Response to TorPharm's Local Rule 56.1(a)(3) Statement of Material Facts
• "SB Noninfringement Add'l Facts"--Plaintiffs' Local Rule 56.1(b)(3) Statement of Additional Facts that Require Denial of TorPharm's Summary Judgment Motion for Noninfringement
• "TP Add'l Facts Resp."--TorPharm's Response to Plaintiff's Local Rule 56.1(b)(3) Statement of Additional Facts That Require Denial of TorPharm's Summary Judgment Motion for Noninfringement

One of the 3-substituted 1-alkyl-4-phenylpiperidine compounds created by Ferrosan was paroxetine. (SB Resp. ¶ 10.) Ferrosan lacked the financial resources to fully commercialize a paroxetine-based drug product (SB Resp. ¶ 31), and on or about July 31, 1980, it licensed its paroxetine*928 technology to the U.K. company Beecham Group Limited ("Beecham"). (*Id.* ¶ 32; TP Exh. 20.) The license granted Beecham the exclusive right to make, have made, use and sell "Paroxetine...(free base or any salt)" throughout the world save in specified Scandinavian countries. (TP Exh. 20.) Pursuant to the license agreement, Ferrosan provided Beecham with information on the chemical structure of paroxetine free base and paroxetine hydrochloride, as well as its method for synthesis of paroxetine hydrochloride and analytical test results. (SB Resp. ¶ ¶ 40-42.)

In the early 1980s, using information obtained from Ferrosan under the license agreement, chemists employed by Plaintiffs ("SmithKline") and located at a pilot plant in Harlow, U.K. worked to improve the process for the manufacture of paroxetine and paroxetine hydrochloride. (SB Resp. ¶ 39-42.) Between 1982 and 1985, the Harlow plant chemists made over 30 batches of paroxetine hydrochloride. (SP Resp. ¶ 41.)

On May 29, 1985, SmithKline scientist Alan Curzons issued a memorandum entitled "Paroxetine Polymorphism." In the memorandum Curzon stated that paroxetine "ha[d] been shown to exist in two discreet [sic] crystalline polymorphic FORMS," a stable, nonhygroscopic hemihydrate and a hygroscopic anhydrate. Curzon further opined that the discovery of the hemihydrate "may offer patent opportunities." The parties dispute whether it was

SmithKline scientists who discovered or "invented" the hemihydrate form of paroxetine or whether the hemihydrate was previously conceived by Ferrosan and communicated to SmithKline under the license agreement. They also disagree as to whether and to what extent SmithKline knew during this period that paroxetine in any form would work as an antidepressant.

On October 25, 1985, Plaintiff Beecham Group p.l.c. ("Beecham"), a British corporation, filed a patent application with GB Application Serial Number 8526407 in the British Patent Office ("GB 8526407"). GB 8526407 "relate [d] to crystalline paroxetine hydrochloride, its preparation and its use as a therapeutic agent." (TP Exh. 48, p. 1.) In it, Beecham specified that the subject invention provided both the hemihydrate and anhydrate forms of crystalline paroxetine hydrochloride, as well as mixtures that contained a major proportion of either form. (*Id.*, p. 3.)

A year later, on October 23, 1986, Beecham filed a patent application in the U.S. Patent and Trademark Office. (TP ¶ 3.) The application included six claims:

1. Crystalline paroxetine hydrochloride hemihydrate.
2. Crystalline paroxetine hydrochloride hemihydrate in substantially pure form.
3. Crystalline paroxetine hydrochloride hemihydrate, having substantially the same X-ray diffractogram as set out in FIG. 1, substantially the same IR spectrum, in a Nujol mull, as set out in FIG. 2, and substantially the same DSC profile as set out in FIG. 3.
4. A process for the preparation of crystalline paroxetine hydrochloride hemihydrate, which process comprises forming a solution of paroxetine hydrochloride and crystallizing said hemihydrate from solution by precipitation or recrystallization.
5. An anti-depressant pharmaceutical composition comprising an effective anti-depressant amount of crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier.
6. A method of treatment of depression in mammals, which method comprises administering an effective amount ***929** of crystalline paroxetine hydrochloride hemihydrate.

The application eventually issued on January 26, 1988, as United States Patent 4,721,723 ("the '723 patent"), the patent in suit. (*Id.*) The '723 patent, entitled "Anti-depressant Crystalline Paroxetine Hydrochloride Hemihydrate," [FN2] relates to an invention that, according to the Abstract, "provides crystalline paroxetine hydrochloride hemihydrate, processes for its preparation, compositions containing the same and its therapeutic use as an anti-depressant." (*Id.*)

> FN2. This compound is characterized by a molecular structure in which two paroxetine hydrochloride molecules are bound to one water molecule in each of the repeating internal unit cells of the crystal.

On November 1, 1995, Beecham assigned the '723 patent, which is due to expire on December 29, 2006, to Plaintiff SmithKline Beecham Corporation ("SmithKline Beecham"). (SB Resp. ¶ 143.) SmithKline Beecham is a Pennsylvania corporation engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world. Pursuant to the '723 patent, SmithKline markets a paroxetine hemihydrate-based product in the United States under the trademark Paxil®. (SB Public Use Exh. 1 ¶ 3.) Paxil is indicated for use in the treatment of depression, obsessive compulsive disorder, and panic disorder. (*Id.*) According to SmithKline, Paxil is one of the most widely prescribed prescription drugs in the United States. (*Id.*)

In or about May 1998, Defendant TorPharm, Inc. ("TorPharm"), a Canadian corporation, through its United States agent Defendant Apotex Corp. ("Apotex"), filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration for "Paroxetine HCl Tablets." The application contained a "Paragraph IV" certification stating that, to the best of TorPharm's knowledge, the '723 patent would not be infringed by the manufacture, use or sale of the proposed paroxetine HCl Tablets. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about May 12, 1998, TorPharm sent SmithKline a 21 U.S.C. § 355(j)(2)(B) Notice of Certification informing it of the filing of the ANDA. The letter offered the following factual and legal basis for TorPharm's assertion that its proposed product would not infringe the '723 patent:

> TorPharm's Paroxetine HCl does not fall within the scope of any of the claims of United States Patent No. 4,721,723 (the '723 patent). All of the claims of the '723 patent are directed to a crystalline paroxetine hydrochloride hemihydrate. TorPharm's Paroxetine HCl is anhydrous.

On June 26, 1998, SmithKline timely filed this patent infringement action pursuant to 35 U.S.C. § 271(e), which makes it an act of infringement to file

an ANDA for a drug claimed in a patent. TorPharm answered the complaint and asserted four affirmative defenses, including the invalidity of the patent under 35 U.S.C. § § 101, 102, 103, and/or 112 and estoppel by reason of statements and representations made to the United States Patent Office to induce the grant of the '723 patent.

In the matter at hand, four of the motions address the validity of the '723 patent. SmithKline asserts that the patent is not invalidated by 35 U.S.C. § 102(f) and (g) and that the hemihydrate was not in public use for more than a year before the patent issued, which would place the substance in the public domain and render it unpatentable. TorPharm has filed a cross-motion on the public use issue and seeks to have the patent invalidated on the grounds that its language is fatally indefinite. Finally, ***930** if we deem the patent valid, TorPharm seeks summary judgment that their proposed drug will not infringe the '723 patent.

LEGAL STANDARD

Summary judgment is appropriate when the record, viewed in the light most favorable to the nonmoving party, reveals that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). The moving party bears the initial burden of showing that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The burden then shifts to the nonmoving party to show through specific evidence that a triable issue of fact remains on issues on which the nonmovant bears the burden of proof at trial. *Id.* The nonmovant may not rest upon mere allegations in the pleadings or upon conclusory statements in affidavits; it must go beyond the pleadings and support its contentions with proper documentary evidence. *Id.*

The plain language of Rule 56(c) mandates the entry of summary judgment against a party who fails to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. "In such a situation there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 323, 106 S.Ct. 2548.

[1] A patent is presumed to be valid, and the burden of demonstrating the invalidity of a patent is on the party asserting the invalidity. 35 U.S.C. § 282. This burden does not shift to the patent holder at any point during the litigation. *T.P. Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971 (Fed.Cir.1984). It is with these principles in mind that we turn to the merits of the motions before us.

DISCUSSION

I. Prior Conception or Anticipation

In their second amended answer to the complaint, TorPharm raises four affirmative defenses. The first states that the '723 patent is invalid because it fails to comply with "one or more of the provisions of 35 U.S.C. § § 101, 102, 103 and/or 112." Despite this sweeping statement, which could implicate any combination of no fewer than 10 statutory subsections, the parties restricted their briefs on this issue to discussion of only § 102(f) and (g). As we are not inclined to engage in an exercise tantamount to statutory roulette, we similarly limit our treatment to those two subsections.

To eliminate the defense, SmithKline must show that the hemihydrate was not invented prior to Alan Curzons' initial description of it in the 1985 memorandum and that it was not anticipated by Ferrosan's earlier activities with the amorphous anhydrate. TorPharm insists that Ferrosan, not Alan Curzons, invented the hemihydrate and that their invention happened before Curzons' purported isolation of the compound in 1985. Sections 102(f) and (g) state that "[a] person shall be entitled to a patent unless...he did not himself invent the subject matter sought to be patented, or before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it...." To obtain summary judgment on the issue of anticipation, therefore, SmithKline must do one of two things. Either they must show that the hemihydrate did not exist until Curzons first identified it, or they must show that even if Ferrosan did actually make the hemihydrate before 1985, they did not ***931** contemporaneously appreciate that they had done so or communicate their knowledge of the existence of the substance to SmithKline. *See Mycogen Plant Science v. Monsanto Co.*, 243 F.3d 1316, 1335-36 (Fed.Cir.2001).

[2][3][4] Whether a patent is invalid because of prior conception is a question of law. *Fiers v. Revel*, 984 F.2d 1164, 1168 (Fed.Cir.1993). SmithKline, as the holder of the '723 patent, already holds a position of advantage because issued patents are presumed valid. 35 U.S.C. § 282; *Speedco, Inc., v. Estes*, 853 F.2d 909, 913 (Fed.Cir.1988). The presumption of

validity for an issued patent includes a presumption that the original inventor is named. *Maxwell v. K Mart Corp.*, 880 F.Supp. 1323, 1331 (D.Minn.1995). TorPharm asserts that because Curzons first identified the hemihydrate in a batch made according to methods Ferrosan had provided to SmithKline, Ferrosan's methods represented a reduction to practice that renders it the true inventor of the hemihydrate. Even assuming *arguendo* that Ferrosan's method invariably resulted in the production of hemihydrate, TorPharm has given us nothing to indicate that Ferrosan appreciated that it had produced the compound or that it communicated that knowledge to SmithKline. Both of these elements are necessary before a patent can be invalidated by prior conception; "an accidental, unappreciated reduction to practice" will not suffice. *Mycogen*, 243 F.3d at 1336.

TorPharm points to another passage in *Mycogen*, which states that a valid prior conception need not recite each limitation of the claim *in haec verba*. 243 F.3d at 1336. We do not quarrel with the accuracy of that statement of law, but *Mycogen* does not stand for the proposition that the language of the claims is irrelevant, particularly under circumstances such as this case. The very crux of the dispute is the difference between hemihydrate and anhydrate. Ferrosan's scientists not only did not call the substance hemihydrate, they never recognized it to be different from the anhydrous material that was the subject of the '196 patent, assuming that they did actually produce the hemihydrate before Curzons' identification. Without such recognition, Ferrosan cannot be said to have "invented" the hemihydrate, and Curzons was the first to identify the substance and is thus correctly deemed its inventor.

[5] A party seeking to invalidate a patent under § 102 is not restricted to showing only prior invention. An invention is just as unpatentable if it is anticipated by prior art. Anticipation of an invention occurs when a single prior art reference or prior reduction to practice discloses each and every element of a claimed invention. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed.Cir.1989); *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed.Cir.1986), *Transco Products, Inc., v. Performance Contracting, Inc.*, 792 F.Supp. 594, 598 (N.D.Ill.1992). If even one element is excluded from the prior art reference, the party seeking to invalidate the patent will not be able to show anticipation. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574 (Fed.Cir.1984).

[6] Although this alternative basis for invalidity is theoretically available to TorPharm, the same defects in their prior invention argument prevent its actual application to this case. Ferrosan, even assuming that they did in fact produce hemihydrate, never realized that they had done so. They could not communicate to SmithKline something that they did not know, and any prior art reference to which TorPharm could point would be lacking the single most important element of the '723 patent: the hemihydrate element. We therefore conclude that the hemihydrate ***932** was neither anticipated by Ferrosan's activities nor did Ferrosan conceive of the substance prior to Curzons' initial identification.

II. Public Use

Thirty-five U.S.C. § 102(b) sets forth a number of statutory bars to the patentability of an invention. In pertinent part, the section provides that "a person shall be entitled to a patent unless--...(b) the invention was...in public use...in this country, more than one year prior to the date of the application for patent in the United States." Because SmithKline filed its application for the '723 patent on October 23, 1986, the "critical date" for purposes of the § 102(b) public use bar in this case is October 23, 1985; SmithKline began testing the efficacy of the hemihydrate in clinical trials before this date, on May 3, 1985. (TP Public Use Resp.¶ 36.) Both parties have moved for summary judgment on the issue of whether these five months of trials constitute an invalidating "public use" of the invention under § 102(b).

A. Experimental Nature of the Trials

[7] The U.S. trials were conducted according to detailed clinical protocols prepared by SmithKline and approved by the FDA. In each trial, a doctor-investigator administered either paroxetine HCl hemihydrate tablets or a placebo to patients selected according to criteria set forth in the protocols. Five of the seven clinical trials involving the hemihydrate were "double blinded" in that neither the investigator nor the patient was aware whether the drug administered was the paroxetine or the placebo. (TP Public Use Resp. ¶ 41-42.) In none of the trials was the doctor or patient informed that it was hemihydrate, rather than some other polymorphic form of the compound, that was being tested. (TP Public Use Resp. ¶ 70.) Both were, however, aware that the hemihydrate was being administered to some patients as part of the study.

SmithKline controlled the trials in a variety of ways,

including establishing the double blind in certain trials and monitoring investigators to ensure that they were following the clinical protocols SmithKline had established. (SB ¶ 60). None of the named inventors of the '723 patent exerted any direct control over or placed limitations on how patients and doctors used the hemihydrate sent to the United States before the critical date. (SB Resp. ¶ ¶ 371, 373.) Nor did they participate in, supervise, or review the results of the U.S. clinical trials. (SB Resp. ¶ 374.) It was SmithKline, their employer and assignee of the '723 patent, who provided such control and supervision.

The results of the U.S. clinical trials were not included in the application for the '723 patent. (TP Exh. 3.) Indeed, they could not be; none of the double blind studies involving the hemihydrate was completed until December 29, 1986, two months after the patent application was filed. (SB Public Use ¶ 47.) It was not until after this date that SmithKline could dissolve the double blind and begin to analyze the results of the clinical trials with respect to the efficacy of the hemihydrate in treating depression in humans. (*Id.*)

SmithKline argues that the above-described clinical trials constitute an experimental use of the hemihydrate, not a "public use" within the meaning of 35 U.S.C. § 102(b). Courts have long recognized the principle that "an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention--even if such testing occurs in the public eye." *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 64, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998). The reasons for the rule are straightforward:

> ***933** It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a *bona fide* effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. *Pfaff*, 525 U.S. at 64-65, 119 S.Ct. 304 (quoting *Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 137, 7 Otto 126, 24 L.Ed. 1000 (1877)).

In accordance with the goals underlying the experimental use doctrine and the strong public interest in gaining rapid access to useful inventions, courts have limited the types of experimentation that trigger application of the exception. Specifically, the testing must have as its aim "to allow *the inventor* to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application." *In re Hamilton*, 882 F.2d at 1581 (emphasis in original). The experimentation cannot be for the purpose of market testing, *see Smith & Davis Mfg. Co. v. Mellon*, 58 F. 705, 707 (1893) (calling market testing "a trader's, not an inventor's, experiment"), commercial profit, *see Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 8 S.Ct. 122, 31 L.Ed. 141 (1887), or testing for suitability for a customer's unclaimed needs, *see, e.g., Cordant Technology, Inc. v. Alliant Techsystems, Inc.*, 45 F.Supp.2d 398, 406 (D.Del.1999). Nor can it aim to satisfy regulatory testing requirements unrelated to the claimed features of the patented invention. *Pennwalt Corp. v. Akzona, Inc.*, 740 F.2d 1573, 1580 (Fed.Cir.1984) (imposing § 102(b) bar where patentee's testing under Environmental Protection Agency experimental use permit had goal of establishing environmental safety, not effectiveness, of patented pesticide).

Ordinarily, courts have required the testing to be carried out by the inventor or someone under his control or surveillance. Although inventor control is not invariably a threshold requirement for application of the experimental use doctrine, it is an "important" factor, *see In re Hamilton*, 882 F.2d 1576, 1581 (Fed.Cir.1989), and courts have not hesitated to find an invalidating public use where an inventor failed to exert sufficient control over the alleged experimentation. *See, e.g., Egbert v. Lippmann*, 104 U.S. 333, 14 Otto 333, 26 L.Ed. 755 (1881); *Lough v. Brunswick Corp.*, 86 F.3d 1113 (1996); *In re Hamilton*, 882 F.2d 1576 (Fed.Cir.1989); *Magnetics, Inc. v. Arnold Eng'r Co.*, 438 F.2d 72, 74 (7th Cir.1971). *Cf. Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253 (Fed.Cir.2001) (vacating finding of public use where district court ignored evidence that inventor actively sought feedback on experiments). The Federal Circuit has explained that the "factor of control is critically important, because, if the inventor has no control over the alleged experiments, he is not experimenting. If he does not inquire about the testing or receive reports concerning the results, similarly, he is not experimenting." *Lough*, 86 F.3d at 1120.

In this case, none of the named inventors planned, supervised, or exerted control over the clinical trials,

inquired about the testing, or received reports concerning the results. TorPharm argues that this lack of participation negates the suggestion that the inventors were using the trials to perfect their invention or to determine whether it would work for its intended ***934** purpose and renders the trials a public use within the meaning of § 102(b). SmithKline counters that its own supervision and control of the clinical trials was sufficient to demonstrate that they represented an experimental rather than public use of paroxetine HCl hemihydrate.

No published case has directly addressed the question of whether control of the alleged experimentation by the inventor's employer and assignee of the patent would, in the face of an utter lack of participation by the named inventor, satisfy the inventor control requirement of the experimental use doctrine. Several cases have, however, used the term "patentee" rather than "inventor" when discussing the control requirement, and in such cases courts tend to be concerned with the unrestricted testing of an invention by *third parties* unconnected to the inventor or the patent process. *See, e.g., Baxter International, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1060 (Fed.Cir.1996); *Petrolite Corp. v. Baker Hughes, Inc.*, 96 F.3d 1423, 1427- 28 (Fed.Cir.1996). For example in *In re Hamilton,* cited by TorPharm, the Federal Circuit commented, "What is remarkable about the tale of experimental use which has been placed before us in this case is the lack of involvement of either the inventor, James Hamilton, *or his employer and assignee,* Western Printing Machinery." 882 F.2d at 1581. These cases suggest that, in appropriate circumstances, the employer/assignee may control the experimentation process in lieu of the inventor.

This reading of the control requirement is consistent with the goals underlying the experimental use doctrine. It is difficult to imagine how unguided testing by a third party without feedback to the parties seeking the patent might play a role in assisting the patent seekers to refine their invention or demonstrate its efficacy. Where the testing is performed at the behest of a corporation that has invested resources in the development of the invention and that stands to benefit financially from its patenting, on the other hand, the connection is evident. Here, the inventors named in the '723 patent were employed by SmithKline under contracts that transferred to SmithKline all rights to any inventions made during their employment. (Exhs. 1-2 to Pls.' Mem. Opp. TorPharm's Mtn. for Summ. Jdgmt. of Invalidity Based on 35 U.S.C. § 102(b).) It was SmithKline who applied for the '723 patent and to SmithKline that the patent was assigned upon issuance. We conclude that in light of this relationship between SmithKline and the inventors and the rationale behind the experimental use doctrine, the absence of any direct participation by the named inventors in the clinical trials does not itself render the '723 patent invalid.

We also conclude that the control SmithKline actually exercised over the trials was sufficient to demonstrate that the trials were in the nature of experimentation rather than mere commercial use. SmithKline drafted detailed clinical protocols that set forth the manner in which the trials were to be conducted. The protocols instructed investigators on *inter alia* the criteria for selecting patients, the appropriate dosing schedule, and the timing of investigator-patient visits, and they set forth rules regarding the confidentiality of study results. (SB Public Use Exhs. 20-22.) SmithKline met with the investigators to discuss their participation in the hemihydrate trials and had each investigator sign an "Investigator Agreement" stating that the trials would be conducted in accordance with the protocols. (SB Public Use Exhs. 23-24.) Finally, SmithKline employees performed some site visits to ensure that the protocols were being followed. (*See, e.g.,* SB Public Use Exhs. 37 at 29 and 38 at 87:14-21.) These controls were significant and strongly indicate the experimental nature of the clinical trials.

***935** TorPharm argues that SmithKline's confidentiality procedures were insufficient to justify invocation of the experimental use doctrine. Confidentiality of test results is indeed one element of the experimental use analysis. *See Baxter International, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1060 (Fed.Cir.1996). However, total secrecy is not required. *See T.P. Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971-72 (Fed.Cir.1984) (failure of dentist-inventor to obtain confidentiality agreements from subject-patients not indicative of absence of inventor control). It is merely one of several factors. The other factors, including the brief period of time of the precritical date testing and the fact that SmithKline received no payment for the trials, weigh in favor of a finding of experimental use. *See Baxter,* 88 F.3d at 1060. This does not end our inquiry, however, as TorPharm has argued that the period during which SmithKline could experiment with the hemihydrate ended before the critical date because the invention was already "reduced to practice."

B. Reduction to Practice

[8] Numerous Federal Circuit cases have recited the rule that experimental use necessarily ends when the invention at issue is "reduced to practice." *See, e.g., RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061 (Fed.Cir.1989); *Atlantic Thermoplastics Co. v. Faytex Corp.*, 5 F.3d 1477, 1480 (Fed.Cir.1993); *Baxter*, 88 F.3d at 1060-1061. Reduction to practice of a pharmaceutical compound means that the inventor " 'actually prepared the composition and knew it would work.' " *Estee Lauder, Inc. v. L'Oreal S.A.*, 129 F.3d 588, 592 (Fed.Cir.1997) (quoting *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed.Cir.1989)). As discussed above, precritical date experimental use of an invention evades the § 102(b) public use bar only when the experimentation represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose. Because an invention that has been reduced to practice is by definition shown to work for its intended purpose, reduction to practice necessarily ends any effort to perfect the invention and ascertain its effectiveness. It thus concludes the period during which use may be considered experimental for purposes of the § 102(b) bar.

SmithKline argues that the Supreme Court's decision in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998), overturned this rule. In *Pfaff*, the Court reversed a Federal Circuit decision that had held that an invention must be reduced to practice for the on-sale bar of 35 U.S.C. § 102(b) to apply. In so holding, the Court established a two-part test for application of the on-sale bar: (1) the product must have been the subject of a "commercial offer for sale," as opposed to an experimental use; and (2) the product must have been "ready for patenting" at the time the offer was made. *Id.* at 67-68, 119 S.Ct. 304. Although proof of reduction to practice is one method of satisfying the ready-for-patenting prong of the test, the Court held, it is not the only means. *Id.* Rather, an invention that is sufficiently outlined or described to enable persons skilled in the art to practice it may be ready for patenting even if it is not yet reduced to practice. *Id.*

Pfaff thus stands primarily for the proposition that "just because reduction to practice is sufficient evidence of completion [of an invention] does not mean that proof of reduction to practice is necessary in every case." 525 U.S. at 66, 119 S.Ct. 304. The decision does not address the related question of whether a reduction to practice is relevant only to the question of whether the invention is ready for patenting or whether it may also bear on the question of whether the nonprivate use of ***936** the invention was public or experimental. The only post-*Pfaff* Federal Circuit case to mention the issue followed the latter approach, but only in nonbinding dicta. *See Zacharin v. United States*, 213 F.3d 1366, 1368 (Fed.Cir.2000) ("The trial court rejected [the experimental use] argument because the parties stipulated that the invention had been reduced to practice before the [ ] contract was awarded, and once an invention has been reduced to practice, it can no longer meet the experimental use exception. *See RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061, 12 USPQ2d 1449, 1453 (Fed.Cir.1989).")

As discussed above, the reduction to practice rule essentially mirrors the unchallenged requirement that any qualifying experimental use be aimed at perfecting the invention or testing its effectiveness. It is the opinion of this court that the reduction to practice rule set forth in *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061 (Fed.Cir.1989) continues to apply after *Pfaff*. We must therefore proceed to determine whether the invention covered by the '723 patent was reduced to practice prior to the critical date of October 23, 1985. The analysis entails legal questions based on underlying facts. *See Estee Lauder, Inc. v. L'Oreal S.A.*, 129 F.3d 588, 592 (Fed.Cir.1997). To the extent that such facts are undisputed, the issue may be ripe for summary judgment.

[9] "To prove actual reduction to practice, an inventor must establish that he 'actually prepared the composition and knew it would work.' " *Estee Lauder, Inc. v. L'Oreal S.A.*, 129 F.3d 588, 592 (Fed.Cir.1997) (quoting *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed.Cir.1989)). The parties agree that SmithKline had actually prepared the hemihydrate prior to the critical date of October 23, 1985; the dispute is over whether SmithKline knew the hemihydrate was suitable for its intended purpose--treating depression in humans--before that date. SmithKline claims that its earlier laboratory and clinical tests were inconclusive and that the controlled clinical trials in the U.S. were required for it to establish the efficacy of the drug. TorPharm contends that SmithKline knew paroxetine HCl hemihydrate was effective to treat depression before the critical date, and that the U.S. clinical trials were carried out for the sole purpose of meeting stringent FDA regulatory requirements regarding proof of the safety and efficacy of drugs to be sold on the U.S. market.

It is clear from the evidence presented by both parties that SmithKline had, prior to the critical date, some indication that paroxetine HCl hemihydrate was likely to work as an antidepressant in humans. Indeed, to obtain the '196 and '723 patents, Ferrosan and SmithKline represented to the patent office that paroxetine and paroxetine HCl hemihydrate, respectively, were useful as antidepressants. *See* '196 patent, (TP Exh. 4, col. 8, ln. 27; '723 patent, TP Exh. 3, claims 5-6). In the application for the '196 patent, Ferrosan supported its utility claims with in vitro tests performed on rat brains that showed that the serotonin uptake inhibitory activity of paroxetine maleate compared favorably with the inhibitory activity of then-common antidepressant drugs like Imipramine and Amitriptyline. (TP Exh. 4, col. 8, lns. 30-44.) It also determined that paroxetine maleate had fewer cardiovascular side effects in animals than did drugs in the Imipramine family. (*Id.*, col. 8, lns. 44-54.) When SmithKline applied for the '723 patent in October 1985, it provided no additional scientific evidence of the effectiveness of paroxetine in treating depression, relying instead on data recited in the '196 patent. (TP Exh. 3, col. 1.) According to TorPharm, this is because the active moiety in both inventions--paroxetine--is the same; if paroxetine is effective at treating depression when used in the ***937** form of a maleate salt, as in the '196 patent, it will be effective when used in any crystalline form, including hemihydrate.

TorPharm also cites animal and human efficacy studies performed by Ferrosan and SmithKline in Europe in the early 1980s, before Curzons reportedly discovered the hemihydrate. SmithKline denies that these studies demonstrated that paroxetine worked as an antidepressant in humans. It cites design flaws in the studies including the low number and imprecise selection of patients and the absence of the double blind it claims is essential in establishing the efficacy of a drug designed to treat a psychological, rather than physiological, condition. (*See, e.g.,* Decl. of Jeffrey S. Simon, SB Public Use Exh. 14, ¶ 7.) In addition, SmithKline points out that its early clinical trials involving humans and animals utilized anhydrous paroxetine, rather than the hemihydrate covered in the '723 patent. SmithKline disputes TorPharm's suggestion that proof of the effectiveness of the anhydrate sufficed as proof that the hemihydrate, too, would work to treat depression. According to SmithKline's experts, " 'only clinical trials would be sufficient to demonstrate the bioavailability and efficacy of paroxetine HCl hemihydrate as an antidepressant.' " (Decl. of Dr. Stephen R. Byrn, attached as Exh. 5 to Pls.' Mem. Opp. TorPharm's Mtn. for Summ. Jdgmt. Based on 35 U.S.C. § 102(b), ¶ ¶ 26-28.) Such trials, SmithKline argues, were not begun with the hemihydrate until May 1985, and the results were not in until after the '723 patent application was filed. TorPharm would have us hold that controlled clinical trials involving human subjects are, as a matter of law, never required for a pharmaceutical manufacturer to demonstrate that a new drug is effective for its intended purpose. The Federal Circuit has held that FDA-mandated testing procedures are not necessary before a pharmaceutical company may *seek a patent* on a new drug. *See In re Brana*, 51 F.3d 1560, 1568 (Fed.Cir.1995); *In re Hartop*, 50 C.C.P.A. 780, 311 F.2d 249, 259-60 (Cust. & Pat.App.1962). However, as the Supreme Court recently noted in *Pfaff, supra,* "[i]t is well settled that an invention may be patented before it is reduced to practice." The cases cited by TorPharm are therefore not dispositive on the reduction to practice issue.

The Federal Circuit has noted that in determining reduction to practice, courts are "guided by a common sense approach in weighing the sufficiency of the testing." *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed.Cir.1994). Humans and rats are not wholly dissimilar, but it is well within the realm of common sense that tests showing decreased uptake of a particular substance in rat brains indicates only a possibility of like chemical behavior in the human cerebrum. It is beyond peradventure that the animal studies would not conclusively prove anything about the effect of such a drug on a complex condition such as human depression and anxiety disorder.

In addition, it is well settled that use in a country other than the United States, without accompanying publication or foreign patent, cannot operate to invalidate an issued American patent. 35 U.S.C. § 102(b) ("[a] person shall be entitled to a patent unless...the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale *in this country,* more than a year prior to the date of the application for patent in the United States") (emphasis added); *see also, e.g., Elizabeth*, 97 U.S. at 130, 7 Otto 126; *Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 589 (7th Cir.1934); *Badowski v. United States*, 143 Ct.Cl. 23, 164 F.Supp. 252, 255 (1958). None of the Ferrosan human or animal trials were conducted within the United States. ***938** The only foreign publication or patent, the British patent application, was filed less than one year before the American application; it

cannot qualify as an invalidating event under § 102(b). Accordingly, SmithKline is entitled to summary judgment that the '723 patent is not invalidated by prior public use.

III. Indefiniteness

TorPharm has moved for summary judgment of invalidity of the '723 patent on the ground that the patent is fatally indefinite within the meaning of 35 U.S.C. § 112. The second paragraph of that section provides that the specification in a patent application "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." TorPharm argues that to the extent that the claims in the '723 patent comply with this section, they cannot support a claim of infringement. To the extent that the claims are construed more broadly to encompass the product identified in TorPharm's ANDA, TorPharm argues, they fail to comply with the particularity requirements of section 112. We address the question of noninfringement in Section IV, *infra,* but because analysis of both indefiniteness and noninfringement hinge on the meaning of the claim language, we begin with a construction of claim 1. *Exxon Research and Engineering Co. v. United States,* 265 F.3d 1371, 1375 (Fed.Cir.2001); *Bayer AG v. Elan Pharmaceutical Res. Co.,* 212 F.3d 1241, 1247 (Fed.Cir.2000).

A. Scope of the Claims

[10] Although we have not performed a formal *Markman* hearing in this case, in light of the parties' full briefing on the issues before us and the oral presentations they have given, we have sufficient information at our disposal to allow us to construe the meaning and scope of claim 1.

Claim 1 of the '723 patent reads simply "[c]rystalline paroxetine hydrochloride hemihydrate." The parties disagree as to the scope of this seemingly plain language. SmithKline contends that claim 1 covers crystalline paroxetine hydrochloride hemihydrate in any amount or in mixtures with other polymorphic forms of paroxetine hydrochloride. TorPharm argues that the claim covers only those paroxetine compositions that consist of pure hemihydrate. According to TorPharm, a paroxetine composition that is primarily anhydrous but contains small numbers of hemihydrate crystals is not covered by the language of the claim. The distinction is a critical one, as SmithKline claims that the product proposed in TorPharm's ANDA, while primarily anhydrous, contains some number of hemihydrate crystals.

[11][12] Three sources of information are properly considered in claim construction: first and foremost, the claims themselves, then the specification and prosecution history if the claim language is not clear on its face. *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (quoting *Unique Concepts, Inc. v. Brown,* 939 F.2d 1558, 1561 (Fed.Cir.1991)); *Gart v. Logitech, Inc.,* 254 F.3d 1334, 1341 (Fed.Cir.2001). Patents must be read in light of their specifications, without reading limitations from the description into a claim. *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.,* 242 F.3d 1337, 1340-42 (Fed.Cir.2001).

[13][14] In construing claim 1 of the '723 patent, we begin from the general principle that "terms in the claim are to be given their ordinary and accustomed meaning." *Gart,* 254 F.3d at 1341. Claim 1 consists of the four words "[c]rystalline paroxetine hydrochloride hemihydrate"; it does not specify whether this compound ***939** must be present alone or may be found in mixtures with other substances or polymorphic forms. Claim 2 sheds some initial light on the question; it reads "[c]rystalline paroxetine hydrochloride hemihydrate in substantially pure form." Under the doctrine of claim differentiation, we may not read into an independent claim a limitation explicitly set forth in another claim. *See, e.g., Environmental Designs Ltd. v. Union Oil Co. of Calif.,* 713 F.2d 693, 699 (Fed.Cir.1983). We therefore cannot interpret claim 1 to contain the "substantially pure" limitation.

[15] TorPharm attempts to reconcile claims 1 and 2 by arguing that "substantially pure" in claim 2 means "substantially free of transesterification by-products." They urge that we look to the specification to determine the meaning of claim 2, but this is unnecessary under the circumstances. Claim 2 is not so unclear that there is no means by which its scope can be ascertained from the plain language used. It is well settled that a patentee can be his or her own lexicographer, using terms in a manner inconsistent with their ordinary meanings. Special definitions given to a word not used according to its ordinary meaning must be clearly defined in the specification, but the written description guides the meaning of the claims even if the guidance does not appear in the express format of a definition. *Markman,* 52 F.3d at 980; *SciMed Life Systems,* 242 F.3d at 1344. SmithKline has not chosen to be its own

lexicographer in the specification by precisely defining the term "substantially pure." TorPharm points to the following passage of the specification, arguing that it creates a limitation on claim 2:

> In the above mentioned U.S. Patent No. 4,007,196, for the preparation of paroxetine (Examples 1 and 2), an N-Methyl compound is reacted with phenyl chloroformate and the resultant compound is hydrolysed with potassium hydroxide.
> One disadvantage of this process is that the solvent used during the hydrolysis step (methyl cellosolve) leads to the production of unwanted transesterification by-products.
> We have now discovered that the purity of the final product can be improved by using a different solvent during the hydrolysis step, such as toluene....
> The pure paroxetine free base thus obtained can then be used for the preparation of crystalline paroxetine hydrochloride hemihydrate as set out above. (TP Exh. 3, col. 3, lines 1-18.)

TorPharm is correct in asserting that this passage sets forth a procedure by which unwanted transesterification by-products are minimized. However, it refers only indirectly to the purity of the final product. The elimination of the transesterifcation by-products occurs during the preparation of the paroxetine free base.[FN3] It does not follow that the only potential impurities that could appear in a substance covered by claim 2 are transesterification by-products. Indeed, claim 2 represents the preferred embodiment of the claimed substance, which would of necessity contain substances other than the hemihydrate to facilitate biodelivery. At most, the passage cited by TorPharm provides one example of an impurity that is eliminated with the patented invention. It does not explicitly limit the meaning of any terms in claim 2.

> FN3. Paroxetine free base refers to the compound paroxetine in isolation, before the hydrochloride is added to form the paroxetine salt and without the crystalline structure or presence of water that distinguish the material named in claim 1.

Because SmithKline has not provided a customized definition of the phrase "substantially pure," we must "give full effect ***940** to the ordinary and accustomed meaning of [the] terms" in claim 2. The ordinary and accustomed meaning of the phrase "in substantially pure form" is "substantially free of any impurities." The term "substantially" could be problematic in that it does not inherently suggest a set range of purity levels. However, the Federal Circuit recently held that the term "substantial," while making the claim language less than ideally precise, leaves those skilled in the art with some indication of its boundaries. *Exxon,* at 1375, 1378. In any event, we need not decide the exact meaning or precision level of this term, because this case does not turn on the language of claim 2. Our only concern is the language of claim 1, which by application of the claim differentiation doctrine cannot be read to contain a limitation of substantial purity, whatever the exact meaning of that term is. In other words, it cannot be read, as TorPharm suggests, to exclude " 'mixtures' and any other composition that contains, but is not purely, crystalline paroxetine hydrochloride hemihydrate." (*See* TP Mem. in Supp. of its Mtn. for Summ. Jdgmt. of Noninfringement, p. 27.)

[16] The hemihydrate, at the time it was patented, was a novel material and so deserving of broader protection than a simple improvement of an existing material. It does not necessarily follow, however, as SmithKline would have us believe, that claim 1 covers any modicum of the hemihydrate found in any mixture with other substances or polymorphic forms. While two distinct claims cannot ordinarily be read to have the same meaning, the doctrine of claim differentiation cannot broaden claims beyond the scope that is supported by the specification. *Multiform Desiccants, Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1480 (Fed.Cir.1998). TorPharm argues along these lines that the specification and prosecution history of the '723 patent impose limits on the invention that exclude from the ambit of claim 1 compositions that are primarily anhydrous but that contain a few incidental crystals of the hemihydrate. We find that the language of claim 1 is sufficiently unclear on this point that consideration of the specification and prosecution history are in fact appropriate. *See Gart,* 254 F.3d at 1341; *see also Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1566 n. 1 (Fed.Cir.1997) (eschewing disputed issue of whether small amounts of patented material present in mixture with public domain material would infringe patent and if so what amounts would be required).

The specification of the '723 patent does not assign a particular nonordinary meaning to any of the terms in claim 1. It does, however, describe certain properties of the substance, such as melting point and water to paroxetine ratio, and enumerates characteristic indicia of the hemihydrate when subjected to certain testing methods such as infrared spectroscopy and X-ray diffractography. *Cf. Amgen, Inc., v. Hoechst*

Marion Roussel, 126 F.Supp.2d 69, 155 (D.Mass.2001) (finding that a detailed description will not distinguish a purportedly novel material when the methods of comparison are based on a "standardless standard"). In addition, the specification describes the hemihydrate as being stable and nonhygroscopic (i.e., not readily absorbing water from the air). These properties distinguish the new material from the prior art anhydrate and thus establish its patentability.

The prosecution history of the '723 patent sheds little illumination on the proper construction of claim 1. At no point did the claim examiner challenge the propriety of its language, giving us no amendments by SmithKline to guide our understanding of exactly what they intended to exclude from claim 1. *See* ***941** *Warner-Jenkinson Co., Inc., v. Hilton Davis Chemical Co.,* 520 U.S. 17, 40- 41, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); *Genentech, Inc., v. Wellcome Foundation Ltd.,* 29 F.3d 1555, 1562 (Fed.Cir.1994). TorPharm greatly emphasizes the language of an earlier British patent application that specifically claimed mixtures of the hemihydrate and anhydrate, insisting that the absence of similar language from the '723 patent disclaims mixtures containing hemihydrate. We disagree with their assessment of the significance of the British application. In at least three places the American patent contemplates substances made up of less than 100% hemihydrate: in claim 2; in the abstract, which refers to compositions containing hemihydrate; and in example 8 of the specification. We will therefore not read the limitations of the British application over the language of the issued American patent.

[17] As recently explained by the Federal Circuit, the proper standard for assessing the definiteness of claim language focuses on one skilled in the art. If such a person "would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2." *Exxon,* at 1375. In other words, the claims at issue need not be perfectly precise but must allow potential competitors some guidance in a prospective determination of whether they are infringing an existing patent. *Exxon,* at 1375. Claims that are difficult to construe are not automatically indefinite; rather a claim must be "insolubly ambiguous" with no proper narrowing construction before it will be deemed invalid for indefiniteness. *Exxon,* at 1375. In addition, issued patents are presumed valid to " protect the inventive contribution of patentees, even when the drafting of their patents has been less than ideal." *Exxon,* at 1375. This statutory presumption requires courts to resolve close questions of indefiniteness in favor of the patent holder. *Exxon,* at 1380.

In light of the holding in *Exxon,* for TorPharm to prevail on this motion, they must prove as a matter of law that one skilled in the art would not understand the bounds of the claim when it is read in light of the specification. This they have not done. The characteristics of the hemihydrate are sufficiently laid out and different enough from those of the anhydrate that the claim is not fatally indefinite. The language satisfies the standard cited in *Exxon,* and it is not invalid for indefiniteness.

IV. Noninfringement

Having concluded that the '723 patent is valid, we must move on to the issue of infringement of the '723 patent. TorPharm moves for summary judgment of noninfringement, alleging that the product identified in its ANDA is an anhydrous form of crystalline paroxetine hydrochloride and thus that it does not fall within the scope of the claims of the '723 patent. SmithKline does not contend that paroxetine hydrochloride anhydrate would infringe the '723 patent. Rather, its complaint centers on a contention that the commercial drug product TorPharm will produce if its ANDA is approved by the FDA will contain crystalline paroxetine hydrochloride hemihydrate and thereby infringe claim 1 of the '723 patent. SmithKline has not moved for summary judgment of infringement, so we consider only whether TorPharm has successfully borne the burden of showing that no genuine issue of material fact exists and that as a matter of law their proposed product will not infringe SmithKline's patent.

A. Testing Methods

[18] As stated earlier, the specification of the patent-in-suit states several distinguishing properties of the claimed substance. Of course, the enumeration of ***942** these properties means little unless their presence in an allegedly infringing substance can be accurately detected and measured. The testing methods employed are therefore an indispensable part of the infringement analysis in this case.

TorPharm argues that the presence of hemihydrate in its proposed product can be measured only using the testing methods to which the patent specifically refers or at least methods that were available at the time the patent issued. To allow SmithKline to use other, newer methods would undermine the notice function

of patents and would cause a patent to mean different things at different times depending on the state of the art in measurement technology. *See Abbott Laboratories v. Alra Laboratories, Inc.*, 1997 WL 667796 (N.D.Ill. Oct. 24, 1997). They insist that the methods discussed in the specification do not show that their product exhibits any of the properties that SmithKline listed as identifying the hemihydrate and thus their proposed drug does not infringe claim 1. They take issue with the testing methods that SmithKline used to determine that their product contained hemihydrate for the purposes of this litigation. They contend that these methods are not the ones cited in the specification and their results are therefore impermissible. SmithKline counters that the tests used to determine infringement need not be the same ones mentioned within the patent language itself, and they claim that the tests they used to measure TorPharm's drug were available when the '723 patent issued. *American Cyanamid Co. v. U.S. Surgical Corp.*, 833 F.Supp. 92, 130-31 (D.Conn.1992) ("proof of infringement is not limited to methods in existence on the date of the invention"); *Cosden Oil & Chemical Co. v. American Hoechst Corp.*, 543 F.Supp. 522, 530 (D.Del.1982) (foreseeing "no advantage and considerable mischief in freezing measurement technology and disregarding new learning which can establish...the precise characteristics of the accused substance"). We agree with these authorities and SmithKline that they are not limited to only the tests to which the patent specifically refers for determining infringement.

B. Timing

[19] Although important, the decision regarding which testing methods are permissible is not the end of the inquiry. The timing of the measurement is also crucial, especially with a substance such as the paroxetine salt, which SmithKline attests will change composition over time and when subjected to everyday temperature and humidity conditions. Given the wide range of possible times for testing, and the correspondingly varying results, the Federal Circuit has ruled that the time at which the composition of a drug proposed in ANDAs is legally significant for infringement purposes is the time of marketing. Any changes in the chemical composition after the product is marketed are simply not relevant to an infringement analysis.

[20] SmithKline makes much of tests it performed simulating the exposure to moisture TorPharm's product would undergo when patients taking the drug repeatedly opened and closed the bottles that contained the drugs. However, because these conditions would occur after the time of marketing, the results of these test are not relevant to our inquiry. TorPharm has supplied us with the levels of purity required of their product both when it ships to them from the supplier of their raw materials, BCI (TP Exhs. 242, 243) and their internal analysis specifications (TP Exhs. 244, 245). However, the numbers in these documents indicate only how much of TorPharm's product is not the crystalline anhydrate, not what substances make up the "contaminants." To decide infringement, we must know whether, and ***943** how much, of the impurity is made up by a demonstrable amount of hemihydrate. Based on the parties' submissions, the facts required for us to make such a determination are very much in dispute, and we therefore cannot find as a matter of law that TorPharm's product does not and cannot infringe the '723 patent.

What amount of hemihydrate is necessary to allow detection of these properties is unclear and necessarily involves issues of fact that are not properly resolved on a motion for summary judgment.

CONCLUSION

For the foregoing reasons, we grant Plaintiffs' motions for summary judgment on the issues of the validity of the '723 patent under 35 U.S.C. § 102(b), (f), and (g). We deny Defendant's motions on the issues of invalidity under 35 U.S.C. § § 102(b) and 112 and noninfringement of the '723 patent.

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